

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David W. JOHNSON *et al.*

Confirmation No.: 1511

Serial No.: 10/698,424

Group Art Unit: 1638

Filed: November 3, 2003

Examiner: Keith O Neal Robinson

For: **ALFALFA PLANTS HAVING IMPROVED STANDABILITY AND/OR FAST
RECOVERY AFTER HARVEST AND METHODS FOR PRODUCING SAME**

Mail Stop Amendment

Commissioner for Patents

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AMENDMENT/RESPONSE TO FINAL REJECTION

This Amendment/Response is responsive to the Final Official Action dated September 12, 2011. This paper is timely submitted with a Request for Continued Examination by January 12, 2012 with a one-month extension of time. Please amend the above-identified patent application in the following manner.

Amendments to the Claims are reflected on the listing of the claims which begins on page 2 of this paper.

Remarks/Responses begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings of claims in this application.

1. (Cancelled)
2. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 10% or greater faster recovery after spring green-up or after harvest.
3. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 20% or greater faster recovery after spring green-up or after harvest.
4. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 30% or greater faster recovery after spring green-up or after harvest.
5. (Cancelled)
6. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 20% or greater more erect stems.
7. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 25% or greater more erect stems.
8. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 30% or greater more erect stems.
9. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 35% or greater more erect stems.

10. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 40% or greater more erect stems.

11. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 45% or greater more erect stems.

12. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 50% or greater more erect stems.

13. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 55% or greater more erect stems.

14. (Previously Presented) The alfalfa variety of claim 15 wherein the alfalfa variety has about 60% or greater more erect stems.

15. (Currently Amended) A *Medicago sativa* alfalfa variety comprising 'French' type alfalfa germplasm and elite alfalfa germplasm adapted to North America, wherein the *Medicago sativa* alfalfa variety has the following characteristics:

(a) 8% or greater faster recovery after spring green-up or after harvest compared to an adapted check variety grown under the same field growing conditions in North America, wherein the adapted check variety is selected from the group consisting of 'WinterGold' and 'Hybri-Force 400', wherein the percentage faster recovery is determined as follows:

- (1) measuring one or more plant heights (the distance from the soil surface to the top of the canopy) to the nearest centimeter, 3-7 days after spring green-up or after harvest, for the alfalfa variety and for one of the adapted check varieties;
- (2) converting the plant heights obtained in step (1) to growth rate (cm/day) by dividing plant height (cm) by the number of days since spring green-up or harvest;

- (3) repeating steps (1 and 2) every few days from 7 to 21 days after spring green-up or harvest;
- (4) calculating an average growth rate per day for the alfalfa variety and the adapted check variety by summing the growth rates per day obtained in steps (2 and 3) and dividing by the number of measurements;
- (5) converting the average growth rate (cm/day) obtained in step (4) to a percentage of the check variety by dividing alfalfa variety growth rate (cm/day) by the check variety growth rate (cm/day) and then multiplying by 100; and
- (6) calculating the percent faster recovery of the alfalfa variety relative to the adapted check variety by subtracting 100 from the alfalfa variety percentage of the check variety percentage obtained in step (5); and

b) 15% or greater more erect stems at late (i.e. 75%) bloom compared to an adapted check variety grown under the same environmental field growing conditions in North America, wherein the adapted check variety is selected from the group consisting of 'WL325HQ' and 'WL319HQ', wherein the percentage of erect stems is determined as follows:

- (1) measuring the percentage of stems standing erect ($>45^\circ$ from the soil surface) of the alfalfa variety and one of the adapted check varieties 30-56 days after spring green-up or last harvest, wherein the measurements are based on the following scale: 0 = 0 to 10% of stems are erect, 1 = 11 to 20% of stems are erect, 2 = 21 to 30% of stems are erect, 3 = 31 to 40% of stems are erect, 4 = 41 to 50% of stems are erect, 5 = 51 to 60% of stems are erect, 6 = 61 to 70% of stems are erect, 7 = 71 to 80% of stems are erect, 8 = 81 to 90% of stems are erect, and 9 = 91 to 100% of stems are erect,
- (2) repeating the stem erectness measurements in step (1) 30-56 days after each harvest thereafter through 75% bloom,

(3) calculating an average stem erectness for the alfalfa variety and the adapted check variety by summing the stem erectness scores obtained in steps (1 and 2) and dividing by the number measurements;

(4) converting the average stem erectness scores obtained in step (3) to a percentage of the adapted check variety by dividing alfalfa variety average stem erectness by the adapted check variety average stem erectness and then multiplying by 100; and

(5) calculating the percent more erect stems of the alfalfa variety relative to the adapted check variety by subtracting 100 from the alfalfa variety percentage of the adapted check variety obtained in step (4).

16. (Previously Presented) A seed of the alfalfa variety of claim 15 or a regenerable part of said seed.

17. (Previously Presented) A pollen of the alfalfa variety of claim 15.

18. (Currently Amended) A seed of an alfalfa plant pollinated by the pollen of claim 17 or a regenerable part of said seed, wherein a plant produced from said seed or regenerable part of the seed has 8% or greater faster recovery after spring green-up or after harvest compared to an adopted check variety grown in the same field growing conditions in North America, wherein the adapted check variety is selected from the group consisting of 'WinterGold' and 'Hybri-Force 400'; and 15% or greater more erect stems at late (i.e. 75%) bloom compared to an adapted check variety grown under the same ~~environmental~~ field growing conditions in North America, wherein the adapted check variety is selected from the group consisting of 'WL325HQ' and 'WL319HQ'.

19. (Previously Presented) An alfalfa plant produced by the seed of claim 16 or produced by a regenerable part of said seed.

20 – 29. (Cancelled).

30. (Currently Amended) A *Medicago sativa* alfalfa variety comprising 'French' type alfalfa germplasm and elite alfalfa germplasm adapted to North America, wherein the *Medicago sativa* alfalfa variety has the following phenotypic characteristics:

(1) faster recovery after spring green-up or after harvest compared to 'WinterGold' or 'Hybri-Force 400' when grown under the same ~~environmental~~ field growing conditions in North America, wherein the faster recovery is selected from the group consisting of about 8% or greater faster recovery, about 10% or greater faster recovery, about 20% or greater faster recovery, and about 30% or greater faster recovery; and

(2) more erect stems at late (i.e. 75%) bloom compared to 'WL325HQ' or 'WL319HQ' when grown under the same ~~environmental~~ field growing conditions in North America, wherein the more erect stems are selected from the group consisting of about 15% or greater more erect stems, about 20% or greater more erect stems, about 25% or greater more erect stems, about 30% or greater more erect stems, about 35% or greater more erect stems, about 40% or greater more erect stems, about 45% or greater more erect stems, about 50% or greater more erect stems, about 55% or greater more erect stems, and about 60% or greater more erect stems.

31. (Previously Presented) The *Medicago sativa* alfalfa variety of claim 15 or claim 30, wherein the 'French' type alfalfa germplasm is 'Flemish' type alfalfa germplasm.

REMARKS

The Final Office Action has been carefully reviewed and the following remarks are made in light of the Action.

Claims 15 and 30 have been amended to recite the limitation that the claimed alfalfa varieties also comprise “elite alfalfa germplasm adapted to North America.” Support for this amendment can be at least found at page 4, lines 22 to 27; page 25, line 14 to page 26, line 21; page 30, line 3 to page 31, line 20; page 35, line 16 to page 37, line 5; and page 40, line 13 to page 42, line 2 of the originally filed specification.

Claims 15, 18 and 30 have been amended to change “same environmental conditions” to “same field growing conditions” for claim consistency. Support for this amendment can be found at least in originally filed claims 1, 5, 15 and 29 and in the ‘Summary of the Invention’ at page 5, lines 15, 18 and 23; and page 6, lines 1, 6, 16, 20 and 25 of the originally filed specification.

Claims 15 and 18 have also been amended to add the further limitation that the field growing conditions are “in North America.” Support for this amendment can be found at least in originally filed claims 1, 5, 15 and 29 and in the ‘Summary of the Invention’ at page 5, lines 15, 18 and 23; and page 6, lines 1, 6, 16, 20 and 25 of the originally filed specification.

No new matter has been added by way of these amendments. Entry and consideration of the foregoing amendments is respectfully requested.

RESPONSE**I. Claim Rejections – 35 USC § 112, First Paragraph – Written Description**

Claims 2-4, 6-19, 30 and 31 remain rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the written description requirement. More specifically, the Examiner alleges that the specification does not identify which conserved germplasm is associated with the claimed traits, and that a representative number of species of plants with the claimed characteristics has not been shown, so that the specification does not convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

Although Applicants do not agree with the rejection, to expedite the examination process, the pending claims have been amended to recite the additional limitation that the claimed alfalfa varieties further comprise “elite alfalfa germplasm adapted to North America.” Furthermore, all of the pending claims now require that the claimed varieties and the check varieties be “grown under the same field growing conditions in North America.” The essence of the present invention is that Applicants were able for the first time to create a new class of alfalfa varieties for production in North America by combining ‘French’ type alfalfa germplasm with elite alfalfa germplasm adapted to North America. See, for example, page 4, line 17 to page 5, line 10 of the as-filed specification. Applicants have for the first time invented a new class of elite alfalfa germplasm with improved standability and fast recovery adapted to North American growing conditions, wherein such varieties are useful for alfalfa production on a large scale. While not wishing to be bound by any particular theory, Applicants believe this invention is the result of gene reshuffling and/or breakage of genetic linkage blocks as a result of their crossing ‘French’

type alfalfa germplasm with elite alfalfa germplasm adapted to North America; and by their subsequent breeding and selecting within the resulting inter-crossed germplasm.

Regarding the Examiner's assertion that the specification does not identify which conserved germplasm is associated with the claimed traits, Applicants respectfully submit that in order to show possession of the claimed invention, there is no burden for the Applicants to show which portion(s) of the 'French' type germplasm or of the elite alfalfa germplasm adapted to North America is contributing to the claimed characteristics. Applicants believe this is a clear error on the part of the Examiner. In fact, as explained immediately below, no Applicant may be able to satisfy the Examiner's unreasonable request considering the nature of the claimed invention and the state of the art of breeding tetraploid alfalfa in 2002, the year during which the priority application of the present invention was filed.

Hill *et al.* (1988, Breeding For Yield and Quality, In Alfalfa and Alfalfa Improvement, Agronomy Monograph Number 29, pages 809 – 825, American Society of Agronomy Inc., Crop Science Society of America Inc., Soil Science Society of America, Inc., Madison, Wisconsin) (copy attached as Exhibit A) state the following in their 'Summary' (Section 26-3, page 823; emphasis added):

Gene action for yield in alfalfa is a type that exhibits heterosis and a severe inbreeding depression. The inbreeding depression is greater than would be expected for autotetraploids on the basis of approach to homozygosity alone. Although conclusive proof has not yet been obtained, heterosis in alfalfa is probably due to effects of linked, dominant, or partially dominant genes. Autotetraploidy and the mode of reproduction in alfalfa make it impossible to utilize heterosis that results from specific combinations of genes or chromosome segments, as can be done with single crosses between diploid, inbred lines. Broad based synthetics provide high levels of heterozygosity with many different heterozygous genotypes, and are probably less sensitive to genotype X environment interactions than narrow based synthetics.

The alfalfa varieties of the present invention are tetraploid. Osborn *et al.* (1998, Molecular Marker Application to Genetics and Breeding of Alfalfa, In Molecular and Cellular Technologies for Forage Improvement, CSSA Special Publication Number 26, pages 25 – 31, Crop Science Society of America, Inc., Madison, Wisconsin) (copy attached as Exhibit B) indicate that although a few molecular markers may have been recently reported for the genetics and breeding of diploid alfalfa populations, “[c]omplete linkage maps are more difficult to develop for tetraploid alfalfa than for diploid alfalfa, and they had not been reported in the literature.” See page 27, first full paragraph of Osborn *et al.*

As far as the Applicants know, it was not until December 2003 (i.e., more than 1 year after the November 1, 2002, priority filing date of the instant application!) that the first near-saturated genetic linkage maps in cultivated tetraploid alfalfa were reported by Julier *et al.* (December 2003, Construction of two genetic linkage maps in cultivated tetraploid alfalfa (*Medicago sativa*) using microsatellite and AFLP markers, MBC Plant Biology, doi: 10.1186/1471-2229-3-9) (copy attached as Exhibit C).

Julier *et al.* mentioned that Brouwer and Osborn (1999, A molecular marker linkage map of tetraploid alfalfa (*Medicago sativa* L.) *Theor. Appl. Genet.* 83:294-300) (copy attached as Exhibit D) constructed a linkage map of tetraploid alfalfa in 1999. However, the map only had 82 RFLP markers with only 7 homology groups, and “the number of polymorphic RFLP markers is clearly a limiting factor to the development of a saturated map at the tetraploid level in alfalfa.” See page 2, left column of Julier *et al.* Julier *et al.* also indicate that “[t]he development of a dense genetic linkage map in cultivated tetraploid alfalfa is the first step in understanding the genetic control (QTLs) of traits of agronomic interest.” See page 4, right column, the first paragraph in Discussion of Julier *et al.*

Thus, the Examiner is asking Applicants to do the “impossible” in requiring that they “identify which conserved germplasm is associated with the claimed traits.” As set forth herein, the genetic tools and methods necessary to provide such information for tetraploid alfalfa was not available in 2002 so that they can now satisfy the Examiner’s requirement being made nearly a decade later in 2011. Clearly, this cannot be the right standard by which Applicants are judged as to the written description requirements of 35 USC § 112, first paragraph.

In fact, possession of the claimed invention can be shown in many ways. See, M.P.E.P. § 2163 II A 3(a). Applicants do not have to show possession specifically by describing the portion(s) of the germplasm that contribute to the phenotypes. Contrary to the Examiner’s assertion, M.P.E.P. § 2163 states at least several ways to show possession:

“Possession may be shown in many ways. For example, **possession may be shown by describing an actual reduction to practice of the claimed invention**. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention . . . **A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose** . . . **Description of an actual reduction to practice of a biological material may be shown by specifically describing a deposit made in accordance with the requirements of 37 CFR 1.801 et seq** . . . An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole . . . **An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention**, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation

between function and structure, or some combination of such characteristics.” (emphasis added)

Applicants have clearly shown possession of the presently claimed invention by actual reduction to practice, at least by following requirements set forth in M.P.E.P. § 2163: (1) by describing at least three exemplary alfalfa varieties (i.e., ‘CW 95026’, ‘CW 83021’, and ‘CW 85029’), each of which meets all of the limitations of the claims; (2) by depositing at least three exemplary alfalfa varieties, each of which meets all of the limitations of the claims; and/or (3) by providing disclosure of sufficiently detailed, relevant identifying characteristics of at least three exemplary alfalfa varieties, each of which meets all of the limitations of the claims. As set forth above, it is unreasonable for the Examiner to now require a written description standard which those skilled in the art say was unattainable at the time of the priority filing date of the present invention. See, for example, Hill *et al.* cited previously.

The Examiner cited *University of California v. Eli Lilly and Co.* 119 F.3d 1559 (Fed. Cir. 1997), alleging that “naming a type of a material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material.” Applicants respectfully submit that the ruling should be read in the context of the facts around the case and the state of the art at the time of the priority filing date of the present invention. In *University of California v. Eli Lilly and Co.*, the cited ruling deals with a claim reciting “mammalian insulin cDNA” without any sequence information of the cDNA. This is not the instant situation. First of all, the plant breeding art involved in the present application is quite different from the molecular biology art which is the subject of *University of California v. Eli Lilly and Co.* A reasonably skilled person in the field of plant breeding would easily recognize upon reading the as-filed specification that Applicants had possession of the claimed invention at the time of filing

it. In addition, Applicants did not just mention the claimed material without providing anything further. Rather, Applicants in the present application disclosed what the claimed materials consist of, and provided sufficiently detailed, relevant identifying characteristics. The claims are specifically directed to *Medicago sativa* alfalfa varieties having 8% or greater recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom when compared to specific commercial check varieties grown under the same field growing conditions in North America, wherein the varieties comprise 'French' type alfalfa germplasm and elite alfalfa germplasm adapted to North America. Furthermore, as discussed above, those skilled in the art of alfalfa breeding recognize that at the time of the priority filing date of the present invention, it was not be possible to identify which conserved germplasm is associated with the claimed traits given that alfalfa is an autotetraploid and not a simple diploid. By disclosing that the claimed varieties are derived from the 'French' type alfalfa varieties and elite alfalfa varieties adapted to North America, and detailed methods of breeding, measuring, and selecting these varieties, Applicants have provided a detailed description of the claimed varieties. Such information disclosed in the present invention is sufficient such that a person skilled in the art of plant breeding would be convinced that Applicants had possession of the claimed invention at the time of filing.

In addition, the Examiner asserts that the specification fails to provide a representative number of species of plants with the claimed characteristics. Applicants also believe this is a clear error on the part of the Examiner. M.P.E.P. § 2163 explains the standard of determining whether there is sufficient written description for claims drawn to a genus, which states in part that:

“The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.” (emphasis added)

Accordingly, possession of a plant genus can be shown by sufficient description of a representative number of species by actual reduction to practice, without disclosing which portion(s) of the germplasm contributes to the claimed phenotypes. Applicants did exactly this. Applicants have shown at least three distinct and representative varieties (i.e., ‘CW 95026’, ‘CW 83021’, and ‘CW 85029’), each of which meets all of the limitations of the claims.

M.P.E.P. § 2163 also explains that, what constitutes a “representative number” is an inverse function of the skill and knowledge in the art:

“What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., *Eli Lilly*. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.”

Instead of one “species” (i.e., variety), Applicants disclosed a representative number of at least three different “species” (i.e., varieties) of alfalfa plants with the claimed characteristics in the present application. In addition, as Applicants have repeatedly asserted both in the

specification, and during the course of prosecuting the present application, anyone skilled in the art of alfalfa variety development can follow the procedures described in the as-filed specification to develop additional varieties (i.e., “species”) which fall within the limitations of the claimed alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late (i.e., 75% bloom) when compared to an adapted check variety grown under the same field growing conditions in North America, as set forth in the claims. Alternatively, one skilled in the art can use any of Applicant’s inventive, disclosed and deposited alfalfa varieties to develop additional alfalfa varieties which meet the claimed limitations.

The attached Declaration by Dr. Johnson (“the Johnson Declaration”) provides further evidence that Applicants have done exactly this (i.e., developed additional *Medicago sativa* alfalfa varieties with the claimed traits by repeating the procedures described in the specification, and/or by using the exemplary, deposited varieties as a source of genetic material in the breeding regime leading to such additional varieties). The Johnson Declaration provides evidence that Applicants have developed at least 21 additional alfalfa varieties directly from ‘French’ type alfalfa germplasm and elite alfalfa germplasm adapted to North America, by repeating the procedures described in the specification. Furthermore, Applicants have developed at least 17 additional varieties derived from one or more of the three exemplary, deposited varieties disclosed in the specification. All 38 of these additional alfalfa varieties meet all of the limitations of the claimed alfalfa varieties. While depositing all of these additional exemplary varieties would be cost prohibitive to Applicants and they believe depositing any of them is unnecessary given that three exemplary varieties have already been deposited under the Budapest Treaty, they are willing to deposit several more representative varieties under the Budapest

Treaty if the Examiner believes that doing so will expedite allowance of the presently pending claims.

The average level of skill in the plant breeding art field is high. One skilled in the art of plant breeding can follow the procedures disclosed by the inventors and use one or more of the exemplified, deposited alfalfa varieties developed by the inventors to produce additional alfalfa varieties having the traits now claimed. The Johnson Declaration provides further evidence that this is doable. Therefore, one skilled in the art of plant breeding would reasonably be convinced that the inventors had possession of the claimed invention at the time the application was filed.

In summary, the specification as-filed teaches detailed methods of making and using the present invention, including all necessary materials to use, and all procedures and standards to follow. The specification also shows a representative number of different species of plants with the claimed characteristics. Three exemplary alfalfa varieties have been deposited under the Budapest Treaty. The references to the teachings of Hill et al. and others clearly establishes that it was not be possible for Applicants to satisfy the selective and restrictive written description requirements asserted by the Examiner, wherein such requirements are not applicable at the time of the priority filing date of the present invention. It is inappropriate for the Examiner to require Applicants to provide that which was theoretically unobtainable in 2002. Therefore, for all of the reasons stated in Applicants' previous responses and as stated above, the specification is written in such a way so as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. The Examiner is respectfully requested to withdraw the rejections under 35 U.S.C. §112 and allow/issue the pending claims.

CONCLUSION

Applicants look forward to allowance of the pending claims or appealing this to the Board of Patent Appeals and Interferences for their consideration of Applicants' responses to each of the rejections, as discussed above. The Examiner is invited to contact the undersigned if necessary to advance prosecution of this application.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 CFR §1.136(a)(3).

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